

(a) They are used or intended for use as plasticizers or lubricants in polystyrene intended for use in contact with food.

(b) They are added to the formulated polymer prior to extrusion.

(c) The quantity used shall not exceed that required to accomplish the intended technical effect.

§ 178.3480 Fatty alcohols, synthetic.

Synthetic fatty alcohols may be safely used as components of articles intended for use in contact with food, and in synthesizing food additives and other substances permitted for use as components of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) The food additive consists of fatty alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except as provided in paragraph (c) of this section.

(b) It is used or intended for use as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted for use as components of articles intended for use in contact with food by existing regulations in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter: *Provided*, That the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted for use as components of food-contact articles.

(c) Synthetic fatty alcohols identified in paragraph (c)(1) of this section may contain not more than 0.8 weight percent of total diols as determined by a method titled "Diols in Monohydroxy Alcohol by Miniature Thin Layer Chromatography (MTLC)," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) *Synthetic fatty alcohols.* (i) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl alcohols meeting the specifications and definition prescribed in § 172.864 of this chapter, except that they may contain not more than 0.8 weight percent total diols.

(ii) Lauryl, myristyl, cetyl, and stearyl alcohols manufactured by the process described in § 172.864(a)(2) of this chapter such that lauryl and myristyl alcohols meet the specifications in § 172.864(a)(1)(i) of this chapter, and cetyl and stearyl alcohols meet the specifications in § 172.864(a)(1)(ii) of this chapter.

(2) *Conditions of use.* (i) Synthetic fatty alcohols as substitutes for the corresponding naturally derived fatty alcohols permitted for use in compliance with § 178.3910.

(ii) Synthetic lauryl alcohol as a substitute for the naturally derived lauryl alcohol permitted as an intermediate in the synthesis of sodium lauryl sulfate used in compliance with § 178.3400.

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 54 FR 24898, June 12, 1989]

§ 178.3500 Glycerin, synthetic.

Synthetic glycerin may be safely used as a component of articles intended for use in packaging materials for food, subject to the provisions of this section:

(a) It is produced by the hydrolysis of carbohydrates, and shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used in a quantity not to exceed that amount reasonably required to produce its intended physical or technical effect, and in accordance with any limitations prescribed by applicable regulations in parts 174, 175, 176, 177, 178 and 179 of this chapter. It shall not be intended to, nor in fact accomplish, any direct physical or technical effect in the food itself.

§ 178.3505 Glyceryl tri-(12-acetoxystearate).

Glyceryl tri-(12-acetoxystearate) (CAS Reg. No. 139-43-5) may be safely

§ 178.3520

21 CFR Ch. I (4–1–05 Edition)

used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The additive is applied to the surface of calcium carbonate at a level not to exceed 1 weight-percent of the total mixture.

(b) The calcium carbonate/glyceryl tri-(12-acetoxystearate) mixture is used as an adjuvant in polymers in contact with nonfatty foods at a level not to exceed 20 weight-percent of the polymer.

[50 FR 1503, Jan. 11, 1985]

§ 178.3520 Industrial starch-modified.

Industrial starch-modified may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) Industrial starch-modified is identified as follows:

(1) A food starch-modified or starch or any combination thereof that has been modified by treatment with one of the reactants hereinafter specified, in an amount reasonably required to achieve the desired functional effect but in no event in excess of any limitation prescribed, with or without subsequent treatment as authorized in § 172.892 of this chapter.

List of reactants	Limitations
Ammonium persulfate, not to exceed 0.3 pct. or in alkaline starch not to exceed 0.6 pct. (4-Chlorobutene-2) trimethylammonium chloride, not to exceed 5 pct. β-Diethylaminoethyl chloride hydrochloride, not to exceed 4 pct. Dimethylaminoethyl methacrylate, not to exceed 3 pct. Dimethylol ethylene urea, not to exceed 0.375 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging. Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging.
2,3-Epoxypropyltrimethylammonium chloride, not to exceed 5 pct. Ethylene oxide, not to exceed 3 pct of reacted ethylene oxide in finished product. Phosphoric acid, not to exceed 6 pct and urea, not to exceed 20 pct.	Industrial starch modified by this treatment shall be used only as internal sizing for paper and paperboard intended for food packaging and as surface sizing and coating for paper and paperboard that contact food only of Types IV-A, V, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter.

(2) A starch irradiated under one of the following conditions to produce free radicals for subsequent graft polymerization with the reactants listed in this paragraph (a)(2):

(i) Radiation from a sealed cobalt 60 source, maximum absorbed dose not to exceed 5.0 megarads.

(ii) An electron beam source at a maximum energy of 7 million electron volts of ionizing radiation, maximum absorbed dose not to exceed 5.0 megarads.

List of reactants	Limitations
Acrylamide and [2-(methacryloyloxy) ethyl]trimethylammonium methyl sulfate, such that the finished industrial starch-modified shall contain: 1. Not more than 60 weight percent vinyl copolymer (of which not more than 32 weight percent is [2-(methacryloyloxy)ethyl] trimethylammonium methyl sulfate).	For use only as a retention aid and dry strength agent employed before the sheet-forming operation in the manufacture of paper and paperboard intended to contact food, and used at a level not to exceed 0.25 pct by weight of the finished dry paper and paperboard fibers.